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In re Application of

Richard M. Lawn et al.

Serial No. 07/969,863

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For: Methods and Deoxyribonucleic Acid for the
Preparation of Tissue Factor Protein

Group Art Unit: 1814

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Morrissey *et al.*, "Properties of Tissue Factor Purified from Human Brain and Placenta", Abs 1632, *Annual Convention of the Amer. Heart Assn.*, abstracts of the 59th Scientific Sessions (1986)

5,110,730, issued 5/5/92, Edgington *et al.*

Kittler, J.M. *et al.*, "Identification of a cDNA Clone for Bovine Tissue Factor", *Federation Proceedings*, 45(6): p. 1639, Ab 927 (1986)

Edgington *et al.*, "Molecular Cloning of Human Tissue Factor cDNA", *Thrombosis and Haemostasis*, 58 (1): 258 (1987)

E. M. Scarpati *et al.*, "Human Tissue Factor: cDNA Cloning, Primary Structure, and Chromosome Localization", *Fed. of Amer. Society for Exp. Biol.*, (78th Annual Mtg), 46 (6) pg.2242, 1 May 1987, 6/7/87-6/11/87, Paper #1846 (ABS)

J. H. Morrissey *et al.*, "Molecular Cloning of the cDNA for Human Tissue Factor", *Fed. of Amer. Society for Exp. Biol.*, (71st Annual Mtg), 46(3):pg. 716, 1 March 1987, 29 March-2 April 1987, Paper 2338(ABS)

E. K. Spicer *et al.*, "Isolation of cDNA clones coding for human tissue factor: Primary structure of the protein and cDNA", *Proc. Natl. Acad. Sci. USA*, 84(15): 5148-5152 (1987)

E. M. Scarpati *et al.*, "Human Tissue Factor: cDNA Sequence and Chromosome Localization of the Gene", *Biochemistry*, 26(17): 5234-5238 (1987)

J. H. Morrissey *et al.*, "Molecular Cloning of the cDNA for Tissue Factor, the Cellular Receptor for the Initiation of the Coagulation Protease Cascade", *Cell*, 50(1): 129-135 (1987)

K.L. Fisher *et al.*, "Cloning and Expression of Human Tissue Factor cDNA", *Thrombosis Research*, 48(1): 89-99 (1987)

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APR 14 1993
GROUP 1800

A. Guha *et al.*, "Affinity purification of human tissue factor: Interaction of factor VII and tissue factor in detergent micelles", *Proc. Natl. Acad. Sci. USA*, **83**: 299-302 (1986)

Livneh, E. *et al.*, "Large deletions in the cytoplasmic kinase domain of the epidermal growth factor receptor do not affect its lateral mobility", *Biolog. Abstr.*, **82**(1): AB 423 #92239 (1986)

Zuniga, M. C. *et al.*, "Expression and Function of Transplantation Antigens with Altered or Deleted Cytoplasmic Domains", *Cell*, **34**: 535-544 (1983)

Bom *et al.*, "Application of Factor VII-Sepharose Affinity Chromatography in the Purification of Human Tissue Factor Apoprotein", *Thrombosis Research*, **42**: 635-643 (1986)

Kurosawa *et al.*, "Urinary Procoagulant Behaves as Tissue Factor by Promoting Factor VIIa-Catalyzed Activation of Factor X", *Thrombosis Research*, **33**: 595-606 (1984)

Tanaka *et al.*, "Purification of Glycosylated Apoprotein of Tissue Factor from Human Brain and Inhibition of its Procoagulant Activity by a Specific Antibody", *Thrombosis Research*, **40**: 745-756 (1985)

Broze *et al.*, "Purification of Human Brain Tissue Factor", *J. Biol. Chem.*, **260**(20): 10917-10920 (1985)

Bjorklid *et al.*, "Purification and Some Properties of the Protein Component of Tissue Thromboplastin from Human Brain", *Biochem. J.*, **165**: 89-96 (1977)

Bach *et al.*, "Purification and Characterization of Bovine Tissue Factor", *J. Biol. Chem.*, **256**(16): 8324-8331 (1981)

Carson *et al.*, "Tissue Factor Gene Localized to Human Chromosome 1 (1pter→1p21)", *Science*, **229**: 991-993 (1985)

Carson *et al.*, "Plasma High Density Lipoproteins Inhibit the Activation of Coagulation Factor X by Factor VIIa and Tissue Factor", *FEBS Letters*, **132**(1): 37-40 (1981)

Osterud, "Activation pathways of the coagulation system in normal haemostasis", *Scand. J. Haematol.* **32**: 337-345 (1984)

Giercksky *et al.*, "The Effect of Intravenous Injection of Purified Human Tissue Thromboplastin in Rats", *Scand. J. Haematol.*, **16**: 300-310 (1976)

Nemerson, "Characteristics and Lipid Requirements of Coagulant Proteins Extracted from Lung and Brain: the Specificity of the Protein Component of Tissue Factor", *J. Clin. Invest.*, **48**: 322-330 (1969)

Nemerson, "The Phospholipid Requirement of Tissue Factor in Blood Coagulation", *J. Clin. Invest.*, **47**: 72-80 (1968)

Carlsen *et al.*, "Intravenous Injections of Tissue Thromboplastin and Phospholipase C in Sheep", *Thromb. Haemostasis*, **48**(3): 315-319 (1982)

Pitlick *et al.*, "Binding of the Protein Component of Tissue Factor to Phospholipids", *Biochemistry*, **9**(26): 5105-5113 (1970)

Lewis *et al.*, "Effects of intravenous tissue thromboplastin in dogs: Development of an anticoagulant", *J. Lab. Clin. Med.* **60**(2): 261-273 (1962)

Gollub *et al.*, "Thromboplastinase-an Experimental Anti-thrombotic", *Thromb. Diath. Haemorrh.*, **7**: 470-479 (1962)

Nemerson, "The role of lipids in the tissue factor pathway of blood coagulation", *Chem Abs.*, **84**: 314 Ab. No. 84.133467p (1976)

WO 88/07543, pub. 10/6/88

WO 84/01786, pub. 10/5/84

EP 278,776, pub. 8/17/88

WO 88/09817, pub. 12/15/88

EP 244,221, pub. 11/4/87

EP 139,416, pub. 05/02/85

Carson *et al.*, "Lipid activation of coagulation factor III apoprotein (tissue factor) - reconstitution of the protein-membrane complex", *Chem Abs.*, **94**: 244 Ab. No. 94:13337f (1981)

Pitlick, "Concanavalin A Inhibits Tissue Factor Coagulant Activity", *J. Clin. Invest.*, **55**: 175-179 (1975)

Vehar, "Recombinant DNA Technology and Its Impact on Our Understanding of Factor VIII", *Factor VIII/von Willebrand Factor: Biological and Clinical Advances, Proc. Bari Int. Conf.* (S Wichpig, ed), Milan, Italy pgs 267-274 (1986)

Freyssinet *et al.*, "Coextraction of Thrombomodulin and Tissue Factor from Human Placenta: Effects of Concanavalin A and Phospholipid Environment on Activity", *Thrombosis and Haemostasis*, **55(1)**: 112-118 (1986)

Osterud, B., "The Interaction of Human Blood Coagulation Factor VII and Tissue Factor: The Effect of Anti Factor VII, Anti Tissue Factor and Diisopropylfluorophosphate", *Biochem. Biophys. Res. Comm.* **88(1)**: 59-67 (1979)

Carson *et al.*, "Monoclonal Antibodies Against Bovine Tissue Factor, Which Block Interaction with Factor VII", *Blood*, **66(1)**: 152-156 (1985)

Gonmori *et al.*, "The Role of Tissue Thromboplastin in the Development of DIC Accompanying Neoplastic Diseases", *Biblio. Haematol.*, **49**: 23-39 (1983)

Ewan *et al.*, "Production and characterization of a monoclonal antibody (A1-3) binds selectively to activated monocytes and inhibits monocyte procoagulant activity", *J. Immunol.*, **136(7)**: 2408-2415 (1986)

Bach *et al.*, "Human Tissue Factor Contains Thioester-Linked Palmitate and Stearate on the Cytoplasmic Half-Cystine", *Biochemistry*, **27**: 4227-4231 (1988)

Carson *et al.*, "An inhibitory monoclonal antibody against human tissue factor", *Blood*, **70(2)**: 490-493 (1987)

Blakeslee *et al.*, "Scientists Find Long-Sought Key to How Blood Clots", *NY Times*, July 7, 1987

Edge *et al.*, "Deglycosylation of Glycoproteins by Trifluoromethanesulfonic Acid", *Analytical Bioch.*, **118**: 131-137 (1981)

Sojar *et al.*, "A Chemical Method for the Deglycosylation of Proteins", *Archives of Bioch. & Biophys.*, **259(1)**: 52-57 (1987)

W.S. Beck, ed., *Hematology*, MIT Press, pp. 381-382 & 436-437 (1981)

Kemp & Cowman, "Direct immunoassay for detecting *Escherichia coli* colonies that contain polypeptides encoded by cloned DNA segments", *Proc. Natl. Acad. Sci.*, **78(7)**: 4520-4524 (1981)

Skalka & Shapiro, "In situ immunoassays for gene translation products in phage plaques and bacterial colonies", *Gene*, 65-79 (1976)

Svensson & Akusjorvi, "Adenovirus 2 early region 1A stimulates expression of both viral and cellular genes", *EMBO J.*, 3(4): 789-794 (1984)

Berman *et al.*, "Engineering glycoproteins for use as pharmaceuticals", *Trends in Biotechnology*, 3(2): 51-53 (1985)

Little, S. *et al.*, "Functional Properties of Carbohydrate-Depleted Tissue Plasminogen Activator", *Biochemistry*, 23: 6191 (1984)

Maniatis *et al.*, *Mol. Cloning: A Laboratory Manual*, Cold Spring Harbor Lab. (Preface and Summary) p. 433 (1982)

Suggs *et al.*, "Use of synthetic oligonucleotides as hybridization probes: Isolation of cloned cDNA sequences for human β_2 -microglobulin", *Proc. Natl. Acad. Sci.*, 78(11):6613-6617 (1987)

Kongisberg *et al.*, "Molecular Cloning of the cDNA for Human Tissue Factor", *Cell*, 52: 639-640 (1988)

Morrissey *et al.*, "Resolution of Monomeric and Heterodimeric Forms of Tissue Factor, the High Affinity Cellular Receptor for Factor VII", *Thrombosis Res.*, 50: 481-493 (1988)

Morrissey *et al.*, 59th Sci. Sessions (Nov. 19, 1986), *Amer. Heart Assoc., Oral Presentation (Notes)*

Bach *et al.*, 59th Sci. Sessions (Nov. 19, 1986), *Amer. Heart Assoc., Oral Presentation (Notes)*

Rao *et al.*, "Affinity Purification of Human Brain Tissue Factor Utilizing Factor VII Bound to Immobilized Anti-factor VII^{1,2}", *Anal. Biochem.*, 165: 365-370 (1987)

Pepe *et al.*, "Functional Sites on Human Tissue Factor", *FASEB J.*, 2(4): AB#552 (May 1-5 1988)

Kikutani, M. *et al.*, "Molecular Structure of Human Lymphocyte Receptor for Immunoglobulin E", *Cell*, 47: 657-665 (1986)

Watson, J.D. *et al.*, *Recombinant DNA*, W.H. Freeman & Co. New York, pgs. 192-193 (1983)

Morrissey & Edgington, "Molecular Cloning of the cDNA for Human Tissue Factor", *Cell*, 52: 639-640 (1988)

Stryer, *Biochemistry*, 2d ed., pp. 32-36 (1981)

Knuth *et al.*, "Purification of Proteins in the Denatured State", *Protein Purification: Micro to Macro*: Alan R. Liss, Inc., pp. 279-305 (1987)

Light, H., "Protein Solubility, Protein Modifications and Protein Folding", *Biotechniques*, 3(4):298-306 (1985)

Bowie *et al.*, "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", *Science*, 247: 1306-1310 (1990)

DIALOG file 155 Abstract, Accession No. 85120937, Stiles, G., "Deglycosylated mammalian beta 2-adrenergic receptors: effect on radioligand binding and peptide mapping", *Arch. Biochem. Biophys.*, 237(1):65-71(abs. only)(1985)

DIALOG file 155 Abstract, Accession No. 85280464, Jurss *et al.*, "Proteolysis-associated deglycosylation of beta 1-adrenergic receptor in turkey erythrocytes and membranes", *Biochemistry*, 24(13): 3349-3354 (1985)

Delente, J.S., "Glycosylation revisited", *Trends in Biotechnology*, 3(9): 218 (1985)

Jaenicke, R. & Rudolph, R., "Folding Protein", *Protein Structure: A Practical Approach*, Creighton, T.E., ed., IRL Press Oxford, England, ch. 9, pp.191-223 (1989)

Mierendorf *et al.*, "Gene Isolation by Screening λ gt11 Libraries with Antibodies", *Methods in Enzymol.*, 152: 458-469 (1987)

Sambrook *et al.*, "Using Antibodies in Immunological Screening", *Molecular Cloning: A Laboratory Manual*, 2nd Ed., Cold Spring Harbor Lab Press (pp. 12.11-12.12)

Itakura *et al.*, "Expression in *Escherichia coli* of a Chemically Synthesized Gene for the Hormone Somatostatin", *Science*, 198: 1056-1063 (1977)

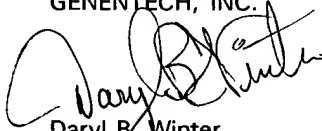
Roberts, T.M., "A *lac* Promoter System for the Overexpression of Prokaryotic and Eukaryotic Genes in *E. coli*," *Promoters: Structure and Function*, Rodriguez & Chamberlin, eds., Praeger Scientific, pubs., pp. 458-461(1982)

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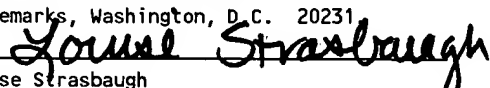


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